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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/536,551	03/28/2000	Dorothy M. Morre'	8951-124-999	5585

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[REDACTED] EXAMINER

WELLS, LAUREN Q

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1617

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/536,551	MORRE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 December 2002.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 12-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 12-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

Claims 12-24 are pending.

***Response to Applicant's Arguments/Amendment***

The Applicant's arguments filed 12/4/02 (Paper No. 16) to the rejection of claims 12-24 made by the Examiner under 35 USC 103 have been fully considered and deemed persuasive. Therefore, the said rejection is hereby withdrawn.

***112 Rejection Maintained***

The rejection of claims 12-24 under 35 U.S.C. 112 is MAINTAINED for the reasons set forth in the Office Action mailed 6/7/02, Paper No. 14, and those found below.

Applicant argues, "Applicants submit that there is no requirement that the specification guarantees the success of the claimed method in identifying every possible chemical compounds". This argument is not persuasive. While this statement is correct, the Examiner respectfully points out that the specification must enable the compounds encompassed by the invention. The Examiner submits that in the instant case, the test compounds have not been enabled.

Applicant argues, "Applicants respectfully submit that ordinary skill in the fields of biochemistry and drug screening technology is high and the specification is enabling for an artisan of ordinary skill to perform the screening assays of the presently claimed invention. The specification has provided methods for isolating and characterizing AR-NOX and thus, based on such teaches, AR-NOX can readily be used in screening assays well known to one of skill in the art". This argument is not persuasive, as this argument is not commensurate in scope with the rejection that was made. The Examiner respectfully points out that the enablement rejection is a

scope of enablement rejection, wherein “test agents”, other than those recited in the claims (cytochrome c) and specification (antibodies), are not enabled for use in the instant method. The Examiner has not made an enablement over the method as a whole. Thus, while the specification may teach methods for isolating and characterizing AR-NOX, the specification is not enabled for test substances that react with AR-NOX.

Applicant argues, “Applicants submit that based on the teachings in the specification and the skill in the art of drug screening, only routine experimentation is required to practice the invention with agents that are not explicitly disclosed in the specification”. This argument is not persuasive. First, the Examiner respectfully points out that great experimentation would be required, and not routine experimentation, to discover what test agents interact with AR-NOX. The Examiner respectfully points out that the term “test agent” encompasses every chemical possibility, ranging from salts to steroids to nucleic acids to peptides to any other chemical compound. Thus, given the infinite number of compounds encompassed by this term and the fantastic difference in chemical properties, a great amount of experimentation would be required to discover what “test substances” can be utilized in the instant method. Furthermore, as taught by Applicant, NOX is present in different isoforms and hence has different chemical properties, so the “test substance” of a CNOX or tNOX would not be the same as that for an AR-NOX. As such, a great amount of experimentation would be required.

Applicant argues, “Applicants respectfully disagree and points out that according to applicable case law. . .an inventor is not required to disclose ‘a test of every species encompassed by their claims’ even in an unpredictable art. . .Moreover, there is no requirement that an application have any working examples, even when the invention involves a complex

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technology". This argument is not persuasive. While the Examiner agrees with Applicant's statements, it is respectfully pointed out that a) while an inventor is not required to disclose 'a test of every species encompassed by their claims', the specification must provide enablement for other species, and b) while there is no requirement for working examples, the specification must provide enablement for their invention. In the instant case, the Examiner respectfully points out that the Applicant has not provided enablement for "test agents".

Applicant argues, "Specific examples of other possible test substances described in the specification. . .include ubiquinone or ubiquinone derivatives. . .and antisense and ribozyme molecules". This argument is persuasive, based on the pages to which Applicant has directed the Examiner. The Examiner respectfully points out that limiting the instant claims to the above test substances (ubiquinone and antisense and ribozyme molecules), to antibodies, and to cytochrome c, will overcome this rejection.

Applicant argues, "As described in the specification. . .binding interactions between two or more components can be measured in a variety of ways known in the art. Methods which measure the activity of AR-NOX are described. . .Thus, Applicants respectfully submit that the specification as filed is enabled for one of skill in the art to screen for agents that sequester AR-NOX comprising incubating AR-NOX with a test agent and detecting an AR-NOX-test agent complex". This argument is not persuasive. The Examiner respectfully points out that the enablement is a scope of enablement rejection, wherein "test agents", other than those recited in the claims (cytochrome c) and specification (antibodies, ubiquinone, antisense and ribozyme molecules), are not enabled for use in the instant method. The Examiner has not made an enablement over the method as a whole. Thus, while the specification may teach methods of

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measuring the activity of AR-NOX, the specification is not enabled for test substances that react with AR-NOX.

Applicant argues, “The Examiner points out that the working examples of the instant specification are directed toward screening methods wherein antibodies are the test substances. Applicants point out that under the applicable case law, it is improper to limit Applicants to the specific example presented”. This argument is not persuasive, as this rejection was not based solely on Applicant’s lack of working example. The lack of working examples was only one factor in determining whether or not the instant invention is enabled for “test substances”. Please see the 112, 1<sup>st</sup> paragraph, rejection in the previous Office Action, which details all the reasons that the instant invention lacks enablement for “test substances”.

Applicant argues, “The instant invention is fully enabled for test agents because (a) the claimed invention is directed to a method of screening for agents that bind AR-NOX, not a method for identifying every chemical compound that bind AR-NOX, (b) screening assays are well known to one of skill in the art, (c) various screening assays are set forth in the specification, and (d) putative test agents, in addition to antibodies, are described in the specification”. This argument is not persuasive. First, the Examiner respectfully points out that without guidance and direction, one of ordinary skill in the art would be forced to undergo undue experimentation to discover what compounds are encompassed by the term “test agent”. Second, while screening assays are well known in the art, “testing agents” that interact with AR-NOX are not. Third, if Applicant limits her claims to specific test agents this rejection will be withdrawn. Fourth, while a few test agents may be recited in the specification, the instant invention still does not provide enablement for “test agents”.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

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lqw  
December 20, 2002

  
SREENI PADMANABHAN  
PRIMARY EXAMINER 12/26/02